

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 8/17/2009 have been fully considered but they are not persuasive.
2. The applicant argues that Counts fails to teach moving a heated zone relative to a compound deposition area to sequentially vaporize portions of a unit dose of a compound on a compound deposition area. The examiner disagrees. As shown in the embodiment of fig. 7h, Counts teaches a slidable heater (771 generates a moving heating zone), a substrate (770) that has a compound deposited as a unit dose on a compound deposition area (770 as a whole can be considered a unit dose). Since the heater is slid able it would sequentially/progressively heat the compound as is slid down 770. The applicant has not stated in the claims the size of the dose or the size of the deposition area. Counts reads on the limitations as claimed.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 7, 8, 10, 13, 19, 32-34, 45, 84, 88-91 are rejected under 35 U.S.C. 102(b) as being anticipated by Counts et al. 5060671.
5. Counts teach a method for delivering a physiologically active compound to a patient comprising the steps of: providing a substrate having first and second ends

upon which a physiologically active compound has been deposited as a unit does on a compound deposition area; generating a moving heating zone that traverses the compound deposition area in a direction from the first end of the second end, thereby sequentially heating compound on the compound deposition area exposed to the heating zone to produce a vapor (col. 7, lines 23-26); allowing the vapor to condense to form an aerosol; and administering the resulting aerosol to a patient; defining a compound deposition area; moving a heating zone with respect to the compound deposition area to progressively vaporize compound exposed to the heating zone (col. 7, lines 23-46); allowing the vapor to condense to form an aerosol (it would be inherent the vapor produced by Counts et al. condenses if the end product is an aerosol); administering the resulting aerosol to a patient; wherein the heating of the compound to form a vapor occurs over a period of 2 seconds or less (col. 5, lines 30-41); wherein the vapor is free of excipients (Counts et al. states that glycerine or water can be added, if not added the compound would be excipient free)

6. As to claim 34, Counts et al. teach the use of the same or similar compounds (nicotine). Those compounds would inherently have the same physical and chemical properties. Therefore the compounds as taught by Counts et al. would inherently vaporized with less than 2%.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claim 4, 29, 85 is rejected under 35 U.S.C. 103(a) as being unpatentable over Counts et al.

9. Counts et al. fails to specifically teach wherein the coating thickness is less than 10 μm . Counts et al. does however teach coating a substrate with a compound. The Applicant has not disclosed that claimed thickness of the coating provides an advantage, is used for a particular purpose, or solves a stated problem. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the claimed thickness, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

10. Claims 5, 6, 30, 31, 86, and 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Counts et al. as applied to claims above, and further in view of Rabinowitz et al. 6783753.

11. Counts et al. teaches the method of claim 19. It should be noted that Counts et al. fails to teach where the aerosol has a mass median aerodynamic diameter of between 1-3 μm or 10-100 nm.

12. Rabinowitz teaches an aerosol that has a mass median aerodynamic diameter of between 1-3 μm or 10-100 nm (col. 3, lines 30-39). Furthermore, it is well known to use the claimed range for aerosols to insure deep inhalation of treatment into the lungs and to prevent sticking of aerosol to delivery devices. Therefore, it would have been

obvious for one having ordinary skill in the art at the time the invention was made to use the claimed range to delivering treatment to the lungs of a patient.

Conclusion

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL G. MENDOZA whose telephone number is (571)272-4698. The examiner can normally be reached on Mon.-Fri. 9:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. G. M./
Examiner, Art Unit 3734

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3734